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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/662,923 | 09/15/2003 | Peter M. Bonutti | 2500DV2CN2DV3CN2 | 2728 |

7590 11/04/2008
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| EXAMINER |
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WOO, JULIAN W

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| ART UNIT | PAPER NUMBER |
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11/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/662,923 | Applicant(s) BONUTTI, PETER M. | |
| | Examiner Julian W. Woo | Art Unit 3773 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-5, 7-9 and 11-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-5, 7-9 and 11-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 26, 2008 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 2, 5, 7-9, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (4,655,746) in view of Kontos et al. (5,180,367).

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Daniels et al. disclose the invention substantially as claimed. Daniels et al. disclose a first tubular member (68) having an open proximal end, a first inflatable member (72), a second tubular member (46) having an open proximal end and an open distal end defining a bore (48) therethrough (col. 4, lines 6-14) and a second inflatable member (30) attached to (via 16) and extending distally from the distal end of the distal end of the second tubular member, where the first and second inflatable members have substantially toroidal configurations, where the first inflatable member has an open distal end defining a second aperture, and where the first inflatable member is attached to and extending distally from the distal end of the first tubular member. However, Daniels et al. fail to disclose that the first inflatable member and first tubular member 68 having an open distal end (since guidewire 74 plugs the distal end of the first inflatable member 72 as indicated in col. 4, lines 54-59). Kontos et al. teach that the tubular member of the inner, pilot balloon can have an open distal end so that it can slidably receive the guidewire instead of being fixed to the guidewire (col. 8, lines 8-19). This arrangement has the self-evident advantage of enabling the position of the tubular member to be adjusted relative to the guidewire. It would have been obvious to make the distal end of the first inflatable member and first tubular member of Daniels et al. open so that they can slidably receive a guidewire so that it too would have this advantage. The slidable guidewire is considered to be the surgical instrument referred to in the claim. Movement of the first inflatable member towards the second inflatable member is inherently capable of capturing body tissue therebetween, particularly since the second inflatable member 30 can be as large as 4 cm in diameter as indicated in

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col. 3, lines 55-59 and since the first inflatable member 72 appears to have a diameter which is comparable to the diameter of the second inflatable member 30 as seen in figure 6.

4. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (4,655,746) in view of Kontos et al. (5,180,367) as applied to claim 2 above, and further in view of Evard et al. (4,981,478). Daniels et al. fail to disclose an inner member defining an annular space with the first tubular member. However, Evard et al. teach that a balloon catheter can be constructed with an inner tubular member (13) and outer tubular member (11) with an annular space therebetween (col. 4, lines 19-30). This arrangement has the advantage of enabling inflation fluid to pass through the annular space and a guidewire to slidably pass through the inner tubular member while maintaining a small profile. It would have been obvious to so construct the Daniels et al. first tubular member so that it too would have this advantage.

5. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels et al. (4,655,746) in view of Kontos et al. (5,180,367) as applied to claim 2 above, and further in view of Mecca (4,690,140). The distal end of first tubular member 68 of Daniels et al., as modified above to be open so that it can slidably receive a guidewire (the claimed surgical instrument) would inherently be capable of receiving an endoscope or laparoscopic instrument since an endoscope or laparoscopic instrument can be as small in diameter as a guidewire. Mecca teaches a very thin endoscopic guide member (1), which is broadly an endoscope since it allows viewing into the area

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(col. 2, lines 10-14 and col. 6, lines 1-9). Note that the surgical instrument itself is not part of the claimed combination.

Response to Amendment

6. Applicant's arguments filed on August 26, 2008 and regarding the rejections based on the reference of Daniel et al. have been fully considered but they are not persuasive. That is, Daniel et al. indeed disclose, inter alia, an apparatus, as claimed, a second inflatable member (30) attached to (via 16) and extending distally from the distal end of the distal end of a second tubular member, which is deemed to be element 46, as best seen in figures 1, 3, and 4. The distal end of element 46 is connected to element 16, which in turn, is connected to the second inflatable member. The second inflatable member extends distally from element 46 in both its uninflated state (see the phantom image of element 30 in figure 4, where the second inflatable member appears to contact element 46) and in its inflated state.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773

November 4, 2008